

*2/12/2005*  
PATENT  
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Janet D'Annunzio-Ellis  
Printed name of person mailing correspondence

*Janet D'Annunzio-Ellis*  
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jack W. Szostak et al.	Art Unit:	1653
Serial No.:	10/004,381	Examiner:	S. Snedden
Filed:	October 31, 2001	Customer No.:	21559
Patent No.:	6,841,359		
Issued:	January 11, 2005		
Title:	STREPTAVIDIN-BINDING PEPTIDES AND USES THEREOF		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth on the Issue Notification mailed on December 23, 2004 in connection with the above-captioned patent application and as indicated on the cover of U.S. Patent 6,841,359 issued on January 11, 2005, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should

be 229 days (i.e., the 233 day period indicated in the Determination of Patent Term

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Adjustment mailed with the Notice of Allowance on July 28, 2004 reduced by Applicants' delay, 4 days, after the mailing date of the Notice of Allowance as detailed below).

In support of this application, Applicants first summarize crucial dates and actions that result in patent term adjustment. The present application was filed on October 31, 2001 and the first action under 35 U.S.C. § 132, a Restriction Requirement, was not mailed until September 23, 2003. The mailing of the restriction requirement was 266 days later than fourteen months from the filing date of the application, resulting in 266 days of patent term adjustment<sup>1</sup>. A non-final Office Action was mailed on February 26, 2004 and Applicants replied to this Office Action on June 28, 2004. Applicants' reply resulted in a reduction of 33 days of patent term adjustment (33 days beyond the three-month time period set forth in 37 C.F.R. § 1.704(b)), for a total adjustment of 233 days (266 days minus 33 days). The Determination of Patent Term Adjustment mailed with the Notice of Allowance correctly set forth the 233-day adjustment. As this calculation was apparently correct, Applicants did not request reconsideration of the patent term adjustment at the time the issue fee was paid.

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<sup>1</sup> The rules governing patent term adjustment due to examination delay are provided for in 37 C.F.R. § 1.702, which states: [T]he term of an original patent shall be adjusted if issuance of the patent was delayed due to the failure of the Office to:(1) Mail at least one notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a).

37 C.F.R. § 1.703 states:

- (a) The period of adjustment under § 1.702(a) is the sum of the following periods:
  - (1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) ... and ending on the mailing date of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

However, the issued patent indicates a revised patent term adjustment and Applicants' calculation of the patent term adjustment period stated on the issued patent differs from that calculated by the Office; Applicants submit that the Office's calculation is in error. The patent term adjustment due to Office delays, 266 days, should be reduced by only 37 days, as detailed below.

On August 3, 2004 (mailed July 29, 2004), after Applicants filed a reply to the February 26, 2004 Office Action, Applicants filed a Supplemental Information Disclosure Statement ("IDS"). This Supplemental IDS was submitted after the mailing date of the Notice of Allowance in this case (but before its receipt by Applicants), and contains a certification under 37 C.F.R. § 1.97(e) that each item of information contained in the IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS.

Under 37 C.F.R. § 1.704(c)(8) circumstances that result in the reduction of the period of adjustment set forth in § 1.703 include:

Submission of a supplemental reply or other paper ... after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

However, under 37 C.F.R. § 1.704(d):

A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information

contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

As noted above, the August 3<sup>rd</sup> IDS contained a statement that each item of information contained in the IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. As shown in Exhibit 1, the communication from the European Patent Office submitted with the August 3<sup>rd</sup> IDS was received by the European attorney handling the case on July 7, 2004 (see the date stamp on the communication). The July 7<sup>th</sup> receipt date is within thirty days of the August 3<sup>rd</sup> date on which the Office received the Supplemental IDS. In view of the above, Applicants submit that the August 3<sup>rd</sup> Supplemental IDS meets the requirements of 37 C.F.R. § 1.704(d) and that the patent term adjustment *should not be reduced* for this submission.

A Notice of Allowance was mailed in this case on July 28, 2004 and Applicants' reply to the Notice of Allowance and Issue Fee payment were received by the Office on November 1, 2004. The Office's November 1<sup>st</sup> receipt date is 4 days beyond the three-month time period set forth in 37 C.F.R. § 1.704(b), resulting in a 4-day reduction in patent term adjustment.

Further, Applicants, with the reply to the Notice of Allowance, filed an Amendment under 37 C.F.R. § 1.312. With this amendment, Applicants resubmitted a

copy of the August 3, 2004 Supplemental IDS and requested that an initialed copy of the Form PTO-1449 included with this IDS be returned to Applicants. On November 17, 2004, the Office acted on the § 1.312 amendment and returned an initialed copy of the requested Form PTO-1449.

37 C.F.R. § 1.704(c)(10) states:

Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

- (i) The number of days, if any, beginning on the date of the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or
- (ii) Four months.

As the Office mailed a response to the November 1, 2004 § 1.312 amendment on November 17, 2004, Applicants submit that the reduction in patent term adjustment due to the § 1.312 amendment should be no more than 17 days.

Moreover, in reviewing the Patent Term Adjustment History on the PAIR system for this case (a printout is attached as Exhibit 2), Applicants note that this delay has been charged to Applicants because the Office apparently considered the resubmission of the August 3<sup>rd</sup> Supplemental IDS with the § 1.312 amendment a submission of a new IDS and therefore a failure by Applicants to engage in reasonable efforts to conclude processing or examination of an application under 37 C.F.R. § 1.704(c). Applicants submit that the basis for the Office's calculation is in error.

The resubmission of the August 3<sup>rd</sup> Supplemental IDS with the November 1<sup>st</sup>

§ 1.312 amendment was necessitated by the *Office's failure* to act on this Supplemental IDS before the issue fee was due. Applicants had not received an initialed copy of the Form PTO-1449 submitted with the August 3<sup>rd</sup> Supplemental IDS and filed the § 1.312 amendment to ensure that the Supplemental IDS was considered by the Office before the patent issued. The August 3<sup>rd</sup> IDS was properly filed in accordance with 37 C.F.R. §§ 1.97 and 1.98 and should have been considered by the Office. Applicants' patent term adjustment should not be reduced for the failure of the Office to provide Applicants with an indication that the Supplemental IDS has been considered by the Office.

In sum, Applicants submit that, in accordance with § 1.704, the patent term adjustment of 266 days should be reduced by only 4 days for the delay in the Office's receipt of the Issue Fee, and 33 days for the delay in replying to the February 26<sup>th</sup> Office Action -- a total of 37 days. This reduction yields a patent term adjustment of 229 days.

As noted above, Applicants' patent term should *not* be reduced because of the filing of the August 3<sup>rd</sup> Supplemental IDS as it falls under the § 1.704(d) exception. Nor is the 17-day reduction for filing the § 1.312 amendment appropriate. Applicants should not be penalized for the Office's failure to act, in a timely manner, on a properly submitted IDS.

In addition, Applicants note that the present patent is not subject to a Terminal Disclaimer.

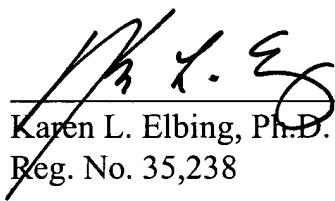
## CONCLUSION

Applicants submit that the current patent term adjustment should be 229 days and request reconsideration of the patent term adjustment.

Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 7 March 2005

  
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- 7. Juli 2004

SEARCH  
FEE

Frist: 16.08.04  
Vorfrist: 06.08.04  
WV: 14.07.04

Datum/Date

16.07.04

Zeichen/Ref./Réf. C62209PCEP	Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./Brevet n° 00990464.0-2405/US0041717
Anmelder/Applicant/Demandeur/Patentinhaber/Propriétaire/Titulaire THE GENERAL HOSPITAL CORPORATION	

B1	30
B2	ROD
B3	
Bekr	Sti
EDV	
Ablg.	

8.7.

## COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 809,--) or the equivalent applicable on the date of payment is payable. This applies also to the search fees requested under Rule 46(1) EPC: See also OJ EPO 06/1999, 405.

The abstract was modified by the Search Division and the definitive text is attached to the present communication.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.



### Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1998.

REGISTERED LETTER



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1 (completely), 4-19 (partially)

A peptide which binds streptavidin with a dissociation constant less than 10 microM, wherein said peptide is not disulfide bonded or cyclized; a nucleic acid encoding said peptide; vector comprising said nucleic acid; a fusion protein comprising a protein of interest linked to said peptide; nucleic acid encoding said fusion protein; vector comprising said nucleic acid; method of producing said fusion protein; method of purifying a protein of interest by the use of said fusion protein; method of detecting the presence of said fusion protein in a sample.

2. Claims: 2 (completely), 4-19 (partially)

A peptide which binds streptavidin with a dissociation constant less than 10 microM, wherein said peptide does not contain an HPQ, HPM, HPN or HQP motif; a nucleic acid encoding said peptide; vector comprising said nucleic acid; a fusion protein comprising a protein of interest linked to said peptide; nucleic acid encoding said fusion protein; vector comprising said nucleic acid; method of producing said fusion protein; method of purifying a protein of interest by the use of said fusion protein; method of detecting the presence of said fusion protein in a sample.

3. Claims: 3 (completely); 4-19 (partially)

A peptide which binds streptavidin with a dissociation constant less than 23 nM; a nucleic acid encoding said peptide; vector comprising said nucleic acid; a fusion protein comprising a protein of interest linked to said peptide; nucleic acid encoding said fusion protein; vector comprising said nucleic acid; method of producing said fusion protein; method of purifying a protein of interest by the use of said fusion protein; method of detecting the presence of said fusion protein in a sample.

The only single general concept which can be identified as linking independent Claims 1-3 is "a peptide which binds streptavidin with a dissociation constant less than 10  $\mu$ M".

However, this common concept is not novel in view of the prior art, see e.g. Katz et al., J. Biol. Chem. Vol. 272 (20), pp. 13220-13228, 1997) and Katz, Biomolecular Engineering, Vol. 16, pp. 57-65, 1999, which disclose HPQ peptides which bind streptavidin with dissociation constants less than 10  $\mu$ M.

Thus, a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 30 EPC is lacking and the requirements for unity of invention referred to in Article 82 EPC are not fulfilled.



European Patent  
Office

**LACK OF UNITY OF INVENTION**  
**SHEET B**

Application Number  
EP 00 99 0464

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Hence, it is considered that the application contains 3 separate inventions as identified above.  
This Partial European Search Report is established on the first invention identified in the claims, i.e. Claim 1 (completely) and Claims 4-19 (partially).

Claims 5 and 6 refer to 30 different sequences which all appear to meet the criteria of Claim 1. Therefore, SEQ ID NOS. 1-29 and 35 form part of the first invention.



European Patent  
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**SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT**  
under Rule 46, paragraph 1 of the European Patent Convention

Application Number  
EP 00 99 0464

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	<p>CHO G ET AL: "Constructing high complexity synthetic libraries of long ORFs using In Vitro selection" JOURNAL OF MOLECULAR BIOLOGY, LONDON, GB, Vol. 297, no. 2, 24 March 2000 (2000-03-24), pages 309-319, XP004461609 ISSN: 0022-2836 * the whole document *</p>	1,4-19	C07H21/02 C07H21/04 C07K1/00 C07K5/00 C12N15/00 C12N15/62 C12Q1/00 G01N33/53
A	<p>KATZ B A: "Streptavidin-binding and dimerizing ligands discovered by phage display, topochemistry, and structure-based design" BIOMOLECULAR ENGINEERING, ELSEVIER, NEW YORK, NY, US, Vol. 16, no. 1-4, 31 December 1999 (1999-12-31), pages 57-65, XP004257799 ISSN: 1389-0344 * page 58, left-hand column, paragraph 2 - page 58, right-hand column, paragraph 1 *</p>	1,4-19 -/-	TECHNICAL FIELDS SEARCHED (Int.Cl.7) C12N
LACK OF UNITY OF INVENTION			
<p>The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:</p>			
<p>see sheet B</p>			
<p>1 The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.</p>			
<p>Place of search</p> <p>MUNICH</p>		<p>Date of completion of the search</p> <p>24 May 2004</p>	<p>Examiner</p> <p>Huber, A</p>
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background D: non-written disclosure P: intermediate document</p> <p>T: theory or principle underlying the invention E: earlier patent document, but published on or after the filing date D: document cited in the application L: document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			



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**SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT**

Application Number  
EP 00 99 0464

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IntCl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	CAPARON M H ET AL: "ANALYSIS OF NOVEL STREPTAVIDIN-BINDING PEPTIDES, IDENTIFIED USING A PHAGE DISPLAY LIBRARY, SHOWS THAT AMINO ACIDS EXTERNAL TO A PERFECTLY CONSERVED CONSENSUS SEQUENCE AND TO THE PRESENTED PEPTIDES CONTRIBUTE TO BINDING" MOLECULAR DIVERSITY, ESCOM SCIENCE PUBLISHERS, LEIDEN, NL, vol. 1, 1995, pages 241-246, XP000884210 ISSN: 1381-1991 * the whole document *	1, 4-19	
T	WILSON DAVID S ET AL: "The use of mRNA display to select high-affinity protein-binding peptides" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, WASHINGTON, US, vol. 98, no. 7, 27 March 2001 (2001-03-27), pages 3750-3755, XP002209215 ISSN: 0027-8424 * the whole document *	1, 4-19	TECHNICAL FIELDS SEARCHED (IntCl.7)
1			



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<b>Patent Term Adjustment (PTA) for application number: 10/004,381</b>	
	Days
Filing or 371(c) Date: 10-31-2001	USPTO Delay (PTO): 266
Issue Date of Patent: 01-11-2005	Three Years: -
Pre-Issue Petitions (days): +0	Applicant Delay (APPL): 199
Post-Issue Petitions (days): +0	Total PTA: 67
USPTO Adjustment (days): +0	Explanation of Calculations

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<b>Patent Term Adjustment History</b>	
Date	Contents Description
12-22-2004	PTA 36 Months
01-11-2005	Patent Issue Date Used in PTA Calculation
12-10-2004	Receipt into Pubs
12-09-2004	Dispatch to FDC
12-09-2004	Application Is Considered Ready for Issue
11-01-2004	Mailroom Date of Issue Fee Payment

4

11-01-2004	Statement Filed Indicating a Loss of Entitlement to Small Entity Status	↑	↑
12-02-2004	Receipt into Pubs	↑	↑
11-17-2004	Mail Response to 312 Amendment (PTO-271)	↑	↑
11-15-2004	Response to Amendment under Rule 312	↑	↑
11-01-2004	Amendment after Notice of Allowance (Rule 312)	↑	17
11-01-2004	Miscellaneous Incoming Letter	↑	55
11-01-2004	Information Disclosure Statement (IDS) Filed	↑	↑
08-03-2004	Information Disclosure Statement (IDS) Filed	↑	90
11-01-2004	Issue Fee Payment Recorded	↑	↑
10-22-2004	Receipt into Pubs	↑	↑
08-27-2004	Sequence Forwarded to Pubs on Tape	↑	↑
08-09-2004	Workflow - File Sent to Contractor	↑	↑
07-28-2004	Mail Notice of Allowance	↑	↑
07-26-2004	Issue Revision Completed	↑	↑
07-26-2004	Notice of Allowance Data Verification Completed	↑	↑
07-26-2004	Notice of Allowability	↑	↑
07-13-2004	Date Forwarded to Examiner	↑	↑
06-28-2004	Response after Non-Final Action	↑	33
06-28-2004	Request for Extension of Time - Granted	↑	↑
06-28-2004	Workflow incoming amendment IFW	↑	↑
02-26-2004	Mail Non-Final Rejection	↑	↑
02-23-2004	Non-Final Rejection	↑	↑
02-05-2004	Date Forwarded to Examiner	↑	↑
01-20-2004	Response to Election / Restriction Filed	↑	↑
12-22-2003	Mail Restriction Requirement	↑	↑
12-18-2003	Requirement for Restriction / Election	↑	↑
10-29-2003	Date Forwarded to Examiner	↑	↑
10-10-2003	Response to Election / Restriction Filed	↑	↑
09-23-2003	Mail Restriction Requirement	266	↑
09-22-2003	Requirement for Restriction / Election	↑	↑
06-08-2002	Case Docketed to Examiner in GAU	↑	↑
06-05-2002	Application Dispatched from OIPE	↑	↑

05-09-2002	<b>Application Is Now Complete</b>	<input type="checkbox"/>	<input type="checkbox"/>
04-15-2002	<b>Additional Application Filing Fees</b>	<input type="checkbox"/>	<input type="checkbox"/>
04-15-2002	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	<input type="checkbox"/>	<input type="checkbox"/>
04-15-2002	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	<input type="checkbox"/>	<input type="checkbox"/>
04-15-2002	Applicant has submitted new drawings to correct Corrected Papers problems	<input type="checkbox"/>	<input type="checkbox"/>
05-03-2002	CRF Is Good Technically / Entered into Database	<input type="checkbox"/>	<input type="checkbox"/>
02-14-2002	Notice Mailed--Application Incomplete--Filing Date Assigned	<input type="checkbox"/>	<input type="checkbox"/>
02-04-2002	IFW Scan & PACR Auto Security Review	<input type="checkbox"/>	<input type="checkbox"/>
12-14-2001	IFW Scan & PACR Auto Security Review	<input type="checkbox"/>	<input type="checkbox"/>
10-31-2001	Initial Exam Team nn	<input type="checkbox"/>	<input type="checkbox"/>

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